DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 4, 2015

Orthogem Ltd.
% Mr. Rod Ruston
Priory Analysts Ltd.
15 Rudchesters
Milton Keynes
BG MK13 0PH
United Kingdom

Re: K150064
Trade/Device Name: Synthetic Bone Graft (TriPore HA, TriPore BP90, TriPore BP15)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 15, 2015
Received: July 20, 2015

Dear Mr. Ruston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150064

Device Name
Synthetic Bone Graft (TriPore HA, TriPore BP90, TriPore BP15)

Indications for Use *(Describe)*
TriPore HA, TriPore BP90, TriPore BP15, is a synthetic bone graft intended to be packed into bone defects of the skeletal system (extremities, posterolateral spine, or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Orthogem. K150064.

510(k) Summary

Submitter/Owner	Orthogem Limited BioCity Pennyfoot Street Nottingham NN1 1GF United Kingdom
Telephone	011 44 115 950 5721
Facsimilie	011 44 115 950 5921
Contact Person	Rod Ruston BSc FRAPS
Date Prepared	23 September 2014
Trade Name	TriPore in a delivery device
Common Name	Synthetic, porous, bone graft granules of: A) hydroxyapatite B) biphasic tri-calcium phosphate:hydroxyapatite. Nominal composition 90:10 C) biphasic tri-calcium phosphate:hydroxyapatite. Nominal composition15:85
Classification	Resorbable calcium salt bone void filler devices have been classified by the Orthopedics Device Panel as Class II Special Controls per 21 CFR 888.3045. Product code: MQV
Predicate Devices	TriPore (K070132) TriPore TDD (K110787)
Device Description	Synthetic bone graft granules of one of the following three materials packed in a multi-purpose applicator (MPA): (A) 100% pure hydroxylapatite (TriPore HA) (B) biphasic mixture of 90% hydroxyapatite and 10% tri-calcium phosphate (TriPore BP90) (C) biphasic mixture of 15% hydroxyapatite and 85% tri-calcium phosphate (TriPore BP15)
Indications for Use	TriPore HA, TriPore BP90 and TriPore BP15 is synthetic bone graft intended to be packed into bone defects of the skeletal system (extremities, spine or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.
Technical Characteristics and Substantial Equivalence	TriPore HA, TriPore BP90 and TriPore BP15 is precisely the same as the predicate device, K070132. When TriPore granules are packed into an applicator, it performs exactly the same function as applicator in the predicate in K110787. The sole difference is the materials and processing used to manufacture the applicator.

(Continued on next page)

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510(k) Summary – continued from previous page

Determination of substantial equivalence (non-clinical data)	Orthogem has determined that TriPore in this application is substantially equivalent to the predicate device on the basis of design verification of the applicator.
Determination of substantial equivalence (clinical data)	No clinical data were submitted. The synthetic bone graft granules are unchanged in composition and manufacture from the predicate device.
Conclusions	Orthogem concludes that the verifications carried out on TriPore in a delivery device demonstrate that it is safe, effective, and performs as well or better than the predicate device.
Other information deemed necessary by the FDA	None.
Summary verification statement	The submitter has verified that this summary includes only information that is also contained in the body of the 510(k). This summary does not contain any: • puffery or unsubstantiated labeling claims • raw data (that is, contains only summary data) • trade secret or confidential information • patient identification information